

TITLE OF THE INVENTION

LONGITUDINALLY FLEXIBLE STENT

RELATED APPLICATIONS

[0001] This application is a continuation-in-part of application 09/864,389 filed on May 25, 2001, which is a continuation-in-part of application 09/795,794 filed on February 28, 2001, which is a non-provisional application of provisional application 60/202,723 filed May 8, 2000 and a continuation-in-part of application 09/516,753 filed on March 1, 2000. The disclosures of the above-identified related applications are hereby incorporated by reference.

FIELD OF THE INVENTION

[0002] The present invention relates generally to stents, which are endoprotheses implanted into vessels within the body, such as, but not limited to, blood vessels, to support and hold open the vessels, or to secure and support other endoprotheses in the vessels. In particular, the present invention relates to a stent which is longitudinally flexible before and after expansion.

BACKGROUND OF THE INVENTION

[0003] Various stents are known in the art. Typically, stents are generally tubular in shape, and are expandable from a relatively small, unexpanded diameter to a larger, expanded diameter. For implantation, the stent is typically mounted on the end of a catheter, with the stent being held on the catheter at its relatively small, unexpanded diameter. By the catheter, the unexpanded stent is directed through the lumen to the intended implantation site. Once the stent is at the intended implantation site, it is expanded, typically either by an internal force, for example by inflating a balloon on the inside of the stent, or by allowing the stent to self-expand, for example by removing a restraining sleeve from around a self-expanding stent, allowing the stent to expand outwardly. In either case, the expanded stent resists the tendency of the vessel to re-narrow, thereby maintaining the vessel's patency.

[0004] U.S. Patent No. 5,733,303 to Israel et al. (" '303"), which is expressly incorporated by reference, shows a unique stent formed of a tube having a patterned shape which has first and second meander patterns having axes extending in first and second directions. The second meander patterns are intertwined with the first meander patterns to form flexible cells. Stents such as this one are very flexible in their unexpanded state such that they can be tracked easily down tortuous lumens. Upon expansion, these stents provide excellent radial support, stability, and coverage of the vessel wall. These stents are also conformable, in that they adapt to the shape of the vessel wall during implantation. It is readily apparent that, by nature, when the stent shown, for example in Fig. 8 thereof, is expanded in a curved lumen, cells on the outside of the curve increase in longitudinal length, but decrease in circumferential width, whereas cells on the inside of the curve decrease in longitudinal length, but increase in circumferential width to maintain a density of stent element area which is much more constant than otherwise between the inside and the outside of the curve.

[0005] One feature of stents with a cellular mesh design such as this one, however, is that they have lower longitudinal flexibility after expansion, which may be a disadvantage in particular applications. This lower longitudinal flexibility may cause stress points at the end of the stent and along the length of the stent. Conventional mesh stents like that shown in U.S. Patent 4,733,665 may simply lack longitudinal flexibility, which is illustrated by Fig. 1, a schematic diagram of a conventional stent 202 in a curved vessel 204.

[0006] To implant an expandable stent, it may be delivered to a desired site by a balloon catheter when the stent is in an unexpanded state. The balloon catheter is then inflated to expand the stent, affixing the stent into place. Due to the high inflation pressures of the balloon - up to 20 atm - the balloon causes the curved vessel 204 and even a longitudinally flexible stent to straighten when it is inflated. If the stent, because of the configuration of its mesh is or becomes relatively rigid in the longitudinal axis after expansion, then the stent remains or tends to remain in the same or substantially the same shape after deflation of the balloon. However, the artery attempts to return to its natural curve (indicated by dashed lines) in Fig. 1 with reference to a conventional mesh stent. The mismatch between the natural curve of the artery and the straightened section of the artery with a stent may cause points of stress concentration 206 at the ends of the stent and stress along the entire stent length. The coronary vasculature can impose additional stress on stents because the coronary vasculature moves relatively significant amounts

with each heartbeat. For illustration purposes, the difference between the curve of the vessel and the straightened stent has been exaggerated in Fig. 1.

[0007] U.S. Patent No. 5,807,404 to Richter, which is expressly incorporated by reference, shows another stent which is especially suited for implantation into curved arterial portions or ostial regions. This stent can include sections adjacent the end of the stent with greater bending flexibility than the remaining axial length of the stent. While this modification at the end of the stent alleviates the stress at the end points, it does not eliminate the stress along the entire length of the stent.

[0008] Various stents are known that retain longitudinal flexibility after expansion. For example, U.S. Patent Nos. 4,886,062 and 5,133,732 to Wiktor ("the Wiktor '062 and '732 patents") show various stents formed of wire wherein the wire is initially formed into a band of zig-zags forming a serpentine pattern, and then the zig-zag band is coiled into a helical stent. The stents are expanded by an internal force, for example by inflating a balloon.

[0009] The coiled zig-zag stents that are illustrated in Figs. 1 through 6 of the Wiktor '062 and '732 patents are longitudinally flexible both, in the expanded and unexpanded condition, such that they can be tracked easily down tortuous lumens and such that they conform relatively closely to the compliance of the vessel after deployment. While these stents are flexible, they also have relatively unstable support after expansion. Furthermore, these stents leave large portions of the vessel wall uncovered, allowing tissue and plaque prolapse into the lumen of the vessel.

[0010] Thus, it is desired to have a stent which exhibits longitudinal flexibility before expansion such that it can easily be tracked down tortuous lumens and longitudinal flexibility after expansion such that it can comply with the vessel's natural flexibility and curvature while still providing continuous, stable coverage of a vessel wall that will minimize tissue sag into the lumen.

SUMMARY OF THE INVENTION

[0011] Accordingly, an object of the invention is to provide a stent that is longitudinally flexible before expansion, so that it can easily be tracked down tortuous vessels and remains

longitudinally flexible after expansion such that it will substantially eliminate any stress points by complying with the vessel's flexibility and assuming the natural curve of the vessel.

[0012] Another object of the present invention is to provide a stent that is longitudinally flexible after delivery such that it flexes during the cycles of the heartbeat to reduce cyclic stress at the ends of the stent and along the stent.

[0013] Another object of the present invention is to provide a stent with a closed cell pattern such that it provides good coverage and support to a vessel wall after expansion.

[0014] Another object of the invention is to minimize the flare-out phenomenon which would otherwise occur during tracking through tortuous anatomies.

[0015] These and other objects are achieved according to the invention by a stent as defined in the claims. Advantages of the present invention will be apparent to those skilled in the art.

[0016] According to the invention, any "flaring out" of loops of the stent during delivery of the stent is minimized by leaving no "free" or unconnected loops of the wide, more rigid struts.

[0017] A stent according to the invention retains the longitudinal flexibility associated with the '303 cellular stent in its unexpanded state, and has increased longitudinal flexibility in the expanded state. The stent does so without sacrificing scaffolding - i.e. coverage of the vessel wall - or radial support.

[0018] In this and other embodiments, cells formed by the meander patterns are such that, when the expanded stent is bent while inside a lumen, the cells on the outside of the curve increase in longitudinal length, but decrease in circumferential width, whereas the cells on the inside of the curve decrease in longitudinal length, but increase in circumferential width, so that the area of the cell and the density of the struts remains much more constant than otherwise. This results in maintaining a more constant density of stent elements in contact with the lumen, irrespective of location on the inside or outside of a curved section. In turn, when the stent is coated with a medicine, a more even dose is applied to the wall of the vessel, avoiding the possibility that a toxic dose be supplied at one area and/or a less than effective dose is applied to another area.

BRIEF DESCRIPTION OF THE DRAWINGS

- Figure 1 shows a schematic diagram of a conventional rigid stent deployed in a curved lumen;
- Figure 2 shows a schematic diagram of a stent of the present invention deployed in a curved lumen;
- Figure 3 shows a pattern for a stent made in accordance with the present invention;
- Figure 4 shows an enlarged view of one cell of the pattern of Figure 3;
- Figure 5 shows a pattern for a stent made in accordance with the present invention;
- Figure 6 shows an enlarged view of one cell of the pattern of Figure 5;
- Figure 7 shows a pattern for a stent made in accordance with the present invention;
- Figure 8 shows an enlarged view of one cell used in the pattern of Figure 7;
- Figure 9 shows an enlarged view of another cell used in Figure 7;
- Figure 10 shows a schematic comparison of a four cornered or "square cell" and a three cornered or "triangular" cell of the present invention;
- Figure 11 shows a pattern for a stent constructed according to the principles of the invention which has variable geometry along its length;
- Figure 12 shows another pattern for a stent constructed according to the principles of the invention;
- Figure 13 shows another pattern for a stent constructed according to the principles of the invention;
- Figure 14 & 14A show the expansion of a portion of a horizontal meander pattern built according to the principles of the invention;
- Figure 15 shows a view of the shape of a single cell on the outside of a curve superimposed on the same cell on the inside of a curve;

Figure 16 shows the ability to compensate for foreshortening of a triangular cell according to the principles of the invention.

Figures 17A-F show other patterns for a stent constructed according to the principles of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0019] Figure 2 shows a schematic diagram of a longitudinally flexible stent 208 of the present invention. The stent 208 may be delivered to a curved vessel 210 by a balloon catheter, and implanted in the artery by inflating the balloon. As described before, the balloon causes the artery to straighten upon inflation of the balloon. However, upon deflation of the balloon, the stent 208 assumes the natural curve of the vessel 210 because it is and remains longitudinally flexible after expansion. This reduces any potential stress points at the ends of the stent and along the length of the stent. Furthermore, because the stent is longitudinally flexible after expansion, the stent will flex longitudinally with the vessel during the systolic cycles. This also reduces any cyclic stress at the ends of the stent and along the length of the stent.

[0020] Figure 3 shows a pattern of a stent according to the present invention. This pattern may be constructed of known materials, and for example stainless steel, but it is particularly suitable to be constructed from NiTi. The pattern can be formed by etching a flat sheet of NiTi into the pattern shown. The flat sheet is formed into a stent by rolling the etched sheet into a tubular shape, and welding the edges of the sheet together to form a tubular stent. The details of this method of forming the stent, which has certain advantages, are disclosed in U. S. Patent Nos. 5,836,964 and 5,997,973, which are hereby expressly incorporated by reference. Other methods known to those of skill in the art such as laser cutting a tube or etching a tube may also be used to construct a stent which uses the present invention. After formation into a tubular shape, a NiTi stent is heat treated, as known by those skilled in the art, to take advantage of the shape memory characteristics of NiTi and/or its superelasticity.

[0021] The pattern 300 is formed from a plurality of each of two orthogonal meander patterns which patterns are intertwined with each other. The term "meander pattern" is taken herein to describe a periodic pattern about a center line and "orthogonal meander patterns" are

patterns whose center lines are orthogonal to each other. It should be clear to any one skilled in the art that a uniform structure with orthogonal meanders can include also meanders drawn in other directions similar to the diagonal lines one can observe when driving around orthogonal patterned plantations.

[0022] A meander pattern 301 is a vertical sinusoid having a vertical center line 302. It will be recognized that this is not a perfect sinusoid, but only an approximation thereof. Thus, as used herein, the term sinusoid refers to a periodic pattern which varies positively and negatively symmetrically about an axis; it need not be an exact sine function. A meander pattern 301 has two loops 304 and 306 per period wherein loops 304 open to the right while loops 306 open to the left. Loops 304 and 306 share common members 308 and 310, where member 308 joins one loop 304 to its following loop 306 and member 310 joins one loop 306 to its following loop 304. The vertical sinusoid of meander pattern 301 has a first frequency. The meander 301 is characterized in that it is expandable in the vertical (circumferential) direction, without placing constraints on its exact direction or the direction of its loops

[0023] A meander pattern 312 (two of which have been shaded for reference) is a horizontal pattern having a horizontal center line 314. A horizontal meander pattern 312 also has loops labeled 316, 318, 320, 322, and between the loops of a period is a section labeled 324. Looked at it in another way, these loops are part of a vertical sinusoid 303 having a vertical center line 305, which has a higher frequency than that of the meander patterns 301. Vertical sinusoids 301 alternate with vertical sinusoids 303. Vertical sinusoids 303 have a second frequency higher than the first frequency of the vertical meander patterns, i.e., sinusoids 301. These meanders are characterized in that they are expandable horizontally (longitudinally). Other non horizontal meanders can be drawn using the same loops but all remain expandable in the horizontal direction (see meander 411 in figure 3).

[0024] Vertical meander pattern 301 is provided in odd and even (o and e) versions which are 180° out of phase with each other. Thus, each left opening loop 306 of meander pattern 301o faces a right opening loop 304 of meander pattern 301e and a right opening loop 304 of meander pattern 301o faces a left opening loop 306 of meander pattern 301e.

[0025] The horizontal meander pattern 312 may also be provided in odd and even forms. The straight sections 324 of the horizontal meander pattern 312e intersect with every third

common member 310 of the even vertical meander pattern 301e. The straight sections 324 of the horizontal meander pattern 312o also intersect with every third common member 310 of the odd vertical meander pattern 301o. Viewed as vertical sinusoids 303, alternating sinusoids 303 are intermittently coupled to the meander patterns 301. For example, between points 315 and 317, where vertical pattern 303 is coupled to vertical pattern 301e, there are two loops 306 and one loop 304 of vertical pattern 301e and three loops 322 and two loops 320 of vertical pattern 303.

[0026] This corresponds to two cycles of pattern 301e and three cycles of pattern 303. Similarly, between two points of coupling between vertical pattern 301o and vertical pattern 303 are two loops 304 and one loop 306, again making two cycles. There will be three loops 320 and two loops 322, again equal to three cycles of pattern 303.

[0027] Since this embodiment of the stent is preferably made of NiTi, and it is reboundable, it typically will be self-expanding. Upon expansion of the stent, the vertical meander patterns 301 open up in the vertical direction. This causes loops in it to shorten in the horizontal direction. The horizontal meander pattern 312 open up in the horizontal direction, compensating for the shortening of the loops of the vertical meander patterns. The loops in the horizontal meander open both in the vertical and the horizontal direction.

[0028] It should be noted that the loops of the horizontal meander pattern 312 or any other meander containing those loops such as 411, which are also the loops of the vertical meander pattern 303 in the present invention, compensate for foreshortening in a self-expanding stent in a particularly effective manner. A self-expanding stent formed of a shape-memory alloy must be compressed from an expanded position to a compressed position for delivery. As shown in Fig. 14, because of the configuration of the loops 320 and 322 of the horizontal meander pattern 312, when the stent is compressed from an expanded position 602 to a compressed position 604, the length 606 of the horizontal meander pattern (width of the vertical pattern 303) naturally shrinks. Consequently, when the stent expands, the loops 320 and 322 elongate and compensate for the shortening of the vertical meander patterns 301e and 301o as the vertical meander patterns 301e and 301o expand. In contrast, a horizontal meander pattern with such shapes as N-shapes will not naturally shrink longitudinally when the stent is compressed from an expanded position 608 to a compressed position 610, as illustrated in Fig. 14. As one skilled in

the art would readily recognize, Fig. 14A has been included to better illustrate the actual resulting configuration of loops 320 and 322.

[0029] A stent formed from the pattern of Fig. 3 and made of NiTi is particularly well suited for use in the carotid artery or other vessels subject to an outside pressure. One reason is that because the stent is formed of NiTi, it is reboundable, which is a desirable property for stents placed in the carotid artery. The other reason is that the stent of Fig. 3 offers excellent scaffolding, which is particularly important in the carotid artery. Scaffolding is especially important in the carotid artery because dislodged particles in the artery may embolize and cause a stroke.

[0030] Figure 4 is an expanded view of one flexible cell 500 of the pattern of Fig. 3. Each flexible cell 500 includes: a first member 501 having a first end 502 and a second end 503; a second member 504 having a first end 505 and a second end 506; a third member 507 having a first end 508 and a second end 509; and a fourth member 510 having a first end 511 and a second end 512. The first end 502 of the first member 501 is joined to the first end 505 of the second member 504 by a first curved member 535 to form a first loop 550, the second end 506 of the second member 504 is joined to the second end 509 of the third member 508 by a second curved member 536, and the first end 508 of the third member 507 is joined to the first end 511 of the fourth member 510 by a third curved member 537 to form a second loop 531. The first loop 550 defines a first angle 543. The second loop 531 defines a second angle 544. Each cell 500 also includes a fifth member 513 having a first end 514 and a second end 515; a sixth member 516 having a first end 517 and a second end 518; a seventh member 519 having a first end 520 and a second end 521; an eighth member 522 having a first end 523 and a second end 524; a ninth member 525 having a first end 526 and a second end 527; and a tenth member 528 having a first end 529 and a second end 530. The first end 514 of the fifth member 513 is joined to the second end 503 of the first member 501 at second junction point 542, the second end 515 of the fifth member 513 is joined to the second end 518 of the sixth member by a fourth curved member 539 to form a third loop 532, the first end 517 of the sixth member 516 is joined to the first end 520 of the seventh member 519 by a fifth curved member 548, the second end 521 of the seventh member 519 is joined to the second end 524 of the eighth member 522 at first junction point 540 to form a fourth loop 533, the first end 523 of the eighth member 522 is joined to the first end 526 of the ninth member 525 by a sixth curved member 549, the second end 527 of the ninth

member 525 is joined to the second end 530 of the tenth member 528 by a seventh curved member 541 to form a fifth loop 534, and the first end 529 of the tenth member 528 is joined to the second end 512 of the fourth member 510 at a third junction point 538. The third loop 532 defines a third angle 545. The fourth loop 533 defines a fourth angle 546. The fifth loop 534 defines a fifth angle 547.

[0031] The first, second, third, fourth and fifth loops 550, 531, 532, 533, 534 are loops directed to the inside of the cell. These loops have no common members with neighboring loops in contradiction to the loops 304, 306, 316, 318, 320 and 322 as defined above.

[0032] In the embodiment shown in Fig. 4, the first member 501, the third member 507, the sixth member 516, the eighth member 522, and the tenth member 528 have substantially the same angular orientation to the longitudinal axis of the stent and the second member 504, the fourth member 510, the fifth member 513, the seventh member 519, and the ninth member 512 have substantially the same angular orientation to the longitudinal axis of the stent. In the embodiment shown in Fig. 4, the lengths of the first, second, third and fourth members 501, 504, 507, 510 are substantially equal. The lengths of the fifth, sixth, seventh, eighth, ninth and tenth members 513, 516, 519, 522, 525, 528 are also substantially equal. Other embodiments where lengths of individual members are tailored for specific applications, materials of construction or methods of delivery are also possible, and may be preferable for them. It can be seen that each cell includes two cycles of the lower frequency vertical pattern and three cycles of the higher frequency vertical pattern.

[0033] The first, second, third, and fourth members 501, 504, 507, 510 may have a width that is greater than the width of the fifth, sixth, seventh, eighth, ninth, and tenth members 513, 516, 519, 522, 525, 528 in that cell. The differing widths of the first, second, third, and fourth members and the fifth, sixth, seventh, eighth, ninth, and tenth members with respect to each other contribute to the overall flexibility and resistance to radial compression of the cell. The widths of the various members can be tailored for specific applications. For example, the ratio of width may be approximately 50-70%. The fifth, sixth, seventh, eighth, ninth, and tenth members may be optimized predominantly to enable longitudinal flexibility, both before and after expansion, while the first, second, third, and fourth members may be optimized predominantly to enable sufficient resistance to radial compression to hold a vessel open. Although specific members may

be optimized to predominantly enable a desired characteristic, all the portions of the cell interactively cooperate and contribute to the characteristics of the stent.

[0034] Figures 5 and 6 show a pattern and an expanded view of one cell of an embodiment of the present invention which is specifically adapted for a balloon expandable stent made of stainless steel or other plastically deforming metal. The pattern is similar to the pattern of Figs. 3 and 4, and the same reference numerals are used to indicate the generally corresponding parts. The stents of the embodiment of Figs. 5 and 6 will normally be expanded by a balloon, in a conventional fashion and the free loops of the low frequency, wide strut rings are made shorter to decrease the effect of flare-out.

[0035] The embodiments of Figs. 3 and 5 can also be viewed as being made up of high frequency and low frequency vertical sinusoidal patterns or vertical loop containing sections which are arranged generally in the circumferential direction and which are periodically interconnected. Thus, there is a first loop containing section with loops occurring at a first frequency extending along line 302 and a second loop containing section with also occurring at said first frequency extending along line 302. A third loop containing section 303 extending along line 305 has loops occurring at a second frequency that is higher than said first frequency. It is disposed between the first and second loop containing sections and alternately joined to the first and second loop containing sections on their respective adjacent edges. In the illustrated embodiment, the high frequency is in a ratio of 3:2 to the low frequency. As noted above, the higher frequency loop containing elements are smaller in width. The relative widths can be selected so that the high frequency elements are crimpable to the same diameter as the lower frequency elements and the flexibility they provide is as desired.

[0036] Furthermore, the high frequency vertical patterns of smaller width result in elements having a lower maximal strain. Specifically, the lower maximal strain may be below the maximum strain without nonelastic deformation for the material the stent is made of. In this embodiment, where the stent is made of stainless steel, the lower maximal strain is below approximately 0.4%, even for a repeated bend bend of about 1 degree per mm length, as confirmed by finite element analysis. On the other hand, in a '303 type stent, for an equivalent amount of bending, a maximum strain of 8% is observed. Thus, the increased flexibility of the

stent of the present invention means that, in addition to conforming better to the curved lumen, it will bend with each beat of the heart and its fatigue resistance will be substantially improved.

[0037] The strain during heart beat happens 8,000,000 times every year and cannot be much above the elastic limit without the stent fracturing. Since embodiments of the present invention keep the strain below the limit means that the stent of the present invention can bend with the vessel as the heart beats for many years with a lower probability of fracture.

[0038] Also in this embodiment of the invention, for example, the second loops 531 are made shorter. This helps assure that the second loops do not "flare out" during delivery of the stent through tortuous anatomy. This "flaring out" is not a concern with NiTi stents which are covered by a sheath during delivery.

[0039] Furthermore, the length of the members in this embodiment may be shorter than the length of the corresponding members in the embodiment illustrated in Figs. 3 and 4. Typically, the amount of strain allowed in a self-expanding NiTi stent may be around 10%. In a stainless steel stent, the amount of strain allowed during the plastic deformation which take place, for example, during expansion, typically may be 20% or greater. Therefore, to facilitate stents made of NiTi and stents made of stainless steel expanding to comparable diameters, the members of the NiTi stent may need to be longer than the members of a stainless steel stent.

[0040] When the stent is within a curved lumen when it is expanded, the stent is curved as shown in Fig. 2. The result of this curving, for a single cell 500, is shown in Fig. 15. The cells on the outside of the curve open in length, but narrow in width whereas the cells on the inside of the curve shorten in length but grow in width. As a result, the density of the members per unit of surface area remains closer to what it is in an uncurved, expanded condition, both on the inside and outside of the curve. Similarly, as can be seen from Fig. 15, the area of the cell remains more constant than it would without such compensation. This results in maintaining a more constant density of stent elements in contact with the vessel wall, irrespective of location on the inside or outside of a curved section. In turn, when the stent is coated with a medicine, a more even dose is applied to the inside wall of the lumen, avoiding the possibility that a toxic dose be supplied at one area while a less than effective dose is applied to another area. In some cases, the ratio between a toxic dose and an effective dose may be smaller than 10:1.

[0041] Specifically, it can be appreciated that, in cells on the outside of the curve at the connection points 535 and 540, the cell will open up increasing the length of the cell. In addition, at the connection points 535, 536, 537, 539, 540 and 541, the adjoining struts will come closer to each other, to cause the cell to become narrower in width, or in the circumferential direction, compensating for the increase in length. On the inside of the curve, the longitudinal distances must decrease. Again, it is easy to see that the compression which occurs on the inside results in the struts on either side of the connection points 542 and 538 being squeezed closed and the length of the cell decreasing. At the same time, at the connection points 535, 536, 537, 539, 540 and 541, the struts will move further apart from each other and the cell becomes more narrow in length but thicker in width again providing compensation. Thus, in both cases, the increase in one direction is compensated by a decrease in the other direction to make the area more constant than it would have been without such compensation.

[0042] Figure 7 illustrates another aspect of the present invention. The stent of Fig. 7 is also constructed from meander patterns in two different directions 301, 312. The meander patterns form a series of interlocking cells 50, 700 of two types. The first type of cell 50 is taught by U.S. Patent No. 5,733,303. These cells may be arranged so that they form alternating bands 704 of the first type of cells 50 and bands 706 of the second type of cells 700. It should be clear to one skilled in the art that the arrangements of different bands may be such as to fit a desired non-uniform anatomy.

[0043] As seen in Fig. 8 and particularly with respect to the cell labeled for ease of description, each of the '303 cells 50 has a first longitudinal apex 100 and a second longitudinal end 78. Each cell 50 also is provided with a first longitudinal end 77 and a second longitudinal apex 104 disposed at the second longitudinal end 78.

[0044] Each cell 50 also includes a first member 51 having a longitudinal component having a first end 52 and a second end 53; a second member 54 having a longitudinal component having a first end 55 and a second end 56; a third member 57 having a longitudinal component having a first end 58 and a second end 59; and a fourth member 60 having a longitudinal component having a first end 61 and a second end 62. The stent also includes a first loop or curved member 63 defining a first angle 64 disposed between the first end 52 of the first member 51 and the first end 55 of the second member 54. A second loop or curved member 65 defining a

second angle 66 is disposed between the second end 59 of the third member 57 and the second end 62 of the fourth member 60 and is disposed generally opposite to the first loop 63. A first flexible compensating member (or a section of a longitudinal meander pattern) 67 having a curved portion and two legs with a first end 68 and a second end 69 is disposed between the first member 51 and the third member 57 with the first end 68 of the first flexible compensating member 67 joined to and communicating with the second end 53 of the first member 51 and the second end 69 of the first flexible compensating member 67 joined to and communicating with the first end 58 of the third member 57. The first end 68 and the second end 69 are disposed a variable longitudinal distance 70 from each other. A second flexible compensating member (or a section of a longitudinal meander pattern) 71 having a first end 72 and a second end 73 is disposed between the second member 54 and the fourth member 60. The first end 72 of the second flexible compensating member 71 is joined to and communicates with the second end 56 of the second member 54 and the second end 73 of the second flexible compensating member 71 is joined to and communicates with the first end 61 of the fourth member 60. The first end 72 and the second end 73 are disposed a variable longitudinal distance 74 from each other. In this embodiment, the first and second flexible compensating members, and particularly the curved portion thereof, 67 and 71 are accurate.

[0045] When curved stent is expanded while inside a lumen, also in the case of the cells 50, cells on the outside of the curve open in length, but narrow in width whereas the cells on the inside of the curve shorten in length, but thicken in width to provide a density of the members per unit of surface area that remains more constant between the inside and outside of the curve.

[0046] Specifically, it can be appreciated that, in cells on the outside of the curve, the flexible connecting members 67 and 71 will open up increasing the distances 70 and 74. In addition, the members 57 and 60 will come closer to each other, as will members 51 and 54. This will further lengthen the cell. But at the same time it will become narrower in width, or in the circumferential direction to compensate for the opening up of the flexible connector members 67 and 71. On the inside of the curve, the longitudinal distances must decrease. Again, it is easy to see that the compression which occurs on the inside results in the loops 67 and 71 being squeezed and the distances 70 and 74 decreasing. At the same time, the members 57 and 60 and members 51 and 54 will move further apart from each other and the longitudinal components of members 57, 60, 51 and 54 will decrease. Thus, the cell becomes narrower in length, but thicker

in width. Thus, in both cases, the increase in one direction is compensated in the other direction to make the area more constant than it would have been without the compensation.

[0047] The second type of cell 700 is illustrated in Fig. 9 and the same reference numerals are used to indicate generally corresponding areas of the cell. The apices 100, 104 of the second type of cell 700 are offset circumferentially. Also, each flexible compensating member 67, 71 includes: a first portion or leg 79 with a first end 80 and a second end 81; a second portion or leg 82 with a first end 83 and a second end 84; and a third portion or leg 85 with the first end 86 and a second end 87, with the second end 81 and the second end 84 being joined by a curved member and the first end 83 and the first end 86 being joined by a curved member. The first end of a flexible compensating member 67, 71 is the same as the first end 80 of the first portion 79, and the second end of a flexible compensating member 67, 71 is the same as the second end 87 of the third portion 85. A first area of inflection 88 is disposed between the second end 81 of the first portion 79 and the second end 84 of the second portion 82, where the curved portion joining them lies. A second area of inflection 89 is disposed between the first end 83 of the second portion 82 and the first end 86 of the third portion 85 where the curved portion joining them lies.

[0048] While Fig. 7 illustrates a pattern of alternating bands of cells, the stent may be optimized for a particular usage by tailoring the configuration of the bands. For example, the middle band of the second type of cells 700 may instead be formed of cells 50, or vice versa. The second type of cells in Fig. 7 may also utilize the cell configurations described with respect to Figs. 4 and 6. The cell configurations of Figs. 4 and 6 provide the advantage that they will not cause any torque of one portion of the cell relative to another portion of the cell about the longitudinal axis of the stent upon expansion, which may happen when the second type of cells 700 expand, a torque which could cause a stent to deform, and stick out.

[0049] As illustrated in Fig. 7, all of the flexible compensating members are arranged so that the path of the flexible compensating members, from left to right, travels in a generally downward direction. The cells 700 can also be arranged so that the flexible compensating members in one band are arranged in a generally upward direction, and the flexible compensating members in an adjacent band are arranged in a generally downward direction. One skilled in the art can easily make these modifications.

[0050] Figure 10 is a schematic representation comparing the cells 804 of the present invention, which have three points where the intertwined first and second meander patterns meet and are in that sense three cornered or triangular cells, with cells 802 of the '303 stent which have four points where the intertwined first and second meander patterns meet and are in that sense four cornered or square cells. More particularly, on the left side of Fig. 10, a pair of vertical meander patterns 806, 826 are joined by members 808, 810, 812 (which are sections of longitudinal meander patterns) to form a plurality of three cornered or triangular cells 804. By triangular cell, it is meant that there are three sections 810, 812, 814, each having loop portions and three associated points 816, 818, 820 of their joining, forming each cell.

[0051] On the right side of Fig. 10, a pair of vertical meander patterns 822, 824 are joined together by compensating members 828, 830, 832, 834 (which are sections of a longitudinal meander) to form a plurality of square cells 802. By square cell it is meant that there are four sections, each having loop portions, and four associated points of their joining, forming each cell. For example, the shaded cell 802 is formed from four sections 832, 836, 830, 838, with four associated points of their joining 840, 842, 844, 846.

[0052] Both, the square cell and the triangular cell, have two kinds of sections with loops. The first kind of loop containing section is formed from a vertical meander pattern and is optimized predominantly to enable radial support. The second kind of loop containing section is optimized predominantly to enable flexibility along the longitudinal axis of the stent. Although each loop containing section is optimized predominantly to enable a desired characteristic of the stent, the sections are interconnected and cooperate to define the characteristics of the stent. Therefore, the first kind of loop containing section contributes to the longitudinal flexibility of the stent, and the second kind of loop containing section contributes to the radial support of the stent.

[0053] In the square cell 802, it can be seen that the second kind of loop containing sections 830, 832 each have one inflection point area 848, 849. In the triangular cell, the loop containing sections 810, 812 each have two inflection point areas 852, 854, 856, 858. The higher number of inflection points allows more freedom to deform after expansion of the stent and distributes the deformation over a longer section, thus, reducing the maximal strain along these loop containing sections.

[0054] Furthermore, it can be seen that a square cell 802 is generally more elongated along the longitudinal axis of the stent than a triangular cell 804, which is generally more elongated along the circumference of the stent. This also contributes to higher flexibility after expansion.

[0055] If the first meander patterns 806, 826 and 822, 824 of both types of cells are constructed identically and spaced apart by the same amount, the area of a triangular cell 804 is the same as the area of a square cell 802. This can be more readily understood with reference to a band of cells around the circumference of a stent. Each band will encompass the same area, and each band will have the same number of cells. Accordingly, the area of each cell in one band formed of square cells will be the same as the area of each cell in another band formed of triangular cells.

[0056] Although the areas of the cells are equal, the perimeter of the triangular cell is larger than the perimeter of the square cell. Therefore, in comparison to a square cell, a triangular cell offers increased coverage of a vessel wall.

[0057] In the particular embodiments described above, the stent is substantially uniform over its entire length. However, other applications where portions of the stent are adapted to provide different characteristics are also possible. For example, as shown in Fig. 11, a band of cells 870 may be designed to provide different flexibility characteristics or different radial compression characteristics than the remaining bands of cells by altering the widths and lengths of the members making up that band. Or the stent may be adapted to provide increased access to a side branch lumen by providing at least one cell 872 which is larger in size than the remaining cells, or by providing an entire band of cells 874 which are larger in size than the other bands of cells. Or the stent may be designed to expand to different diameters along the length of the stent. The stent may also be treated after formation of the stent by coating the stent with a medicine, plating the stent with a protective material, plating the stent with a radiopaque material, or covering the stent with a material.

[0058] Figures 12 and 13 show alternative patterns for a stent constructed according to the principles of the present invention. The stent shown in Fig. 12 has two bands of cells 880 located at each of the proximal end 882 and distal end 884. The cells that form the bands of cells

880 located at the ends of the stent are '303 type cells. The remaining cells in the stent are the same as described with respect to the cells 500 depicted in Fig. 6.

[0059] An embodiment which is particularly useful as a renal stent may have, for example, one band of cells 880 at each end and as few as four bands of cells 500. The geometry of the cells 500 is very soft longitudinally and the nature of most of the renal artery lesions is that they are ostial. With an ostial lesion, a structure made solely of cells 500 may be pushed to elongate and let the lesion prolapse through the elongated (enlarged) cell. In regular lesions, the stent cannot be pushed open because of the friction of the stent on both sides, but in the ostium of the renal artery, where there is no support on the aorta side for the single ring, it is possible.

[0060] Thus, in order to correct this problem, stents whose basic geometry is that of cells 500, but which have the two end bands of cells 880 that have the '303 type geometry are used. This results in a flexible stent before and after deployment, but with a rigid, non-elongating band of cells located at each of the proximal end 882 and distal end 884.

[0061] The stent shown in Fig. 13 has alternating bands of cells 864, 866, 868. The first type of band of cells 64 is composed of '303 type cells. The second and third types of bands of cells 866, 868 are formed of the cells described with respect to the cells 500 depicted in Fig. 6. Of course, any various combination of cells may be used in the present invention.

[0062] Although shown with two bands of '303 type cells at each end, this is not a requirement; there can be more or fewer, nor do the numbers of bands need be the same at both ends. Also, although twelve bands of cells 500 are shown in Fig. 13, a different number may be provided.

[0063] The ability to compensate for foreshortening is further illustrated by Fig. 16. This shows how the loop containing sections 901, which are part of the horizontal meander patterns, and have a higher frequency, compensate for foreshortening of the sections 903, which have a lower frequency when the stent expands. In the upper portion of the figure, both the high frequency loop containing section 901 and the low frequency loop containing section 903 are shown in the compressed condition. The width of the section 903 is from line 905 to line 907. The width of the low frequency section extends from 907 to line 909. The lower portion of the figure shows the stent expanded. The width of the low frequency section 903 is foreshortened and now extends only from line 905 to line 911. However, in expanding the high frequency

section 901 has compensated for this foreshortening. It has a width that now extends from line 911 to line 909, providing compensation for foreshortening without any friction. As noted above, this is particularly advantageous for self expanding stents, e.g. those made of austenitic NiTi, also known under the name Nitinol, that expand to a memorized shape.

[0064] Referring, for example, to Fig. 4, it can be seen that, at a junction point 540, for example, which is also shown in Fig. 16, the high frequency loop is joined to the low frequency loop. This also occurs at junction points 538 and 542. The additional thickness at these points restrains the ability of the loops to open up. On the other hand, loops extending from curved members 548 and 549 are not so restrained. The result is that the angle between members 513 and 516 opens up more than the angle between members 519 and 522, for example. The combined effect of these angles results in the increase in width of the high frequency section which compensates for the foreshortening of the low frequency section.

[0065] The further embodiments presented in figures 17A –F share all the design and functional features of the previously presented embodiments. The additional feature is that the connections between first meanders and second meanders, or between low frequency bands and high frequency bands is such that no free loops of the low frequency band are present. The resulting ratio of frequency is 1:3, as described above, and the first meanders do not have odd and even first meanders. The loops of the high frequency band may be of uneven length and arranged to facilitate manufacturing and smoothness, as presented in figures 17D and 17E. It is clear to one skilled in the art that other arrangements for this purpose could be designed and would be analogous to those presented. The presence of meanders of two types in two different directions in this design is demonstrated in figure 17F. It should be understood that an important feature of this embodiment of the invention is the fact that all loops of the first frequency ring are connected. The ratio of frequencies may be different from 1:3, and the phase relations between rings may be anywhere between in-phase and 180 degrees out of phase.

[0066] Elaborating further, Figures 17A-17F (wherein like reference numbers refer to like parts) illustrate embodiments which eliminate free radially-supporting loops, and can provide increased smoothness along the length of the stent in a bent configuration. In the stent embodiments of Figs. 17A-F, three cycles of a second vertical sinusoid 1010 are interconnected by a single cycle of a first vertical sinusoidal band 1001 to form a cell. This corresponds to three

loops 1016, 1017 and 1018 or 1019 of the second sinusoidal band 1010 for each single loop 1004 or 1006 of the first sinusoidal band 1001, for a loop ratio of 3:1 in forming a cell.

[0067] Referring first to Figures 17A-17C, stent 1000 includes a plurality of first sinusoidal bands (or first loop-containing sections) 1001 generally having one frequency and a plurality of second sinusoidal bands (or second loop-containing sections) 1010 generally having a second frequency. As preferred, the first and second bands may have different wavelengths and both extend in a generally circumferential direction relative to the longitudinal axis of the stent. The first and second bands also preferably alternate with each other in a repeating pattern and are interconnected to each other as indicated by intersections 1025 and 1026, which may be interconnection points, struts or additional curved members, so long as the overall stent possesses a relatively uniform flexibility as taken along its longitudinal direction.

[0068] The first bands 1001 are generally parallel to each other and in phase relative to one another, and the second bands 1010 are likewise arranged generally parallel and in phase to each other. The first and second bands with their intersections (1025 and 1026) form a plurality of cells 1050 that function in a similar fashion to cells described above. Preferably, all cells 1050 have approximately the same area and overall configuration, and are arranged symmetrically about a line parallel to the longitudinal axis of the stent (e.g., center line 1029). This arrangement can provide such further advantages as reducing or eliminating potential stress points at a bend in a vessel. In addition, this configuration can provide highly even scaffolding characteristics, and, further, may be particularly useful for delivering a drug in the form of a drug-eluting stent.

[0069] Also as described above, the width and/or thickness of the strut members 1014a-c may be smaller than the strut members 1005 and 1007. Similarly, the intervening connecting curved segments (1016, 1017, 1018 and/or 1019), which connect respective strut members 1014a-c of the second sinusoidal bands 1010, may also have a different width and/or thickness from either or both first and second bands. For example, the first sinusoidal bands 1001 may have wider strut members than the second bands 1010, with the width selected to provide the desired level of radial support to the blood vessel when the stent is expanded in the vessel, while the second sinusoidal bands 1010 can have narrower portions to optimize, or otherwise provide the desired level of longitudinal flexibility to the stent. The optimization of radial support and

flexibility may be accomplished in a number of different ways, as will be apparent to those skilled in the art, such as by varying width, thickness, length, curvature, frequency and/or material/characteristics (e.g., elasticity) of any of the members making up the strut.

[0070] The amplitude of any sinusoidal band may be generally constant (as generally shown in Figure 17B), or may vary (as shown in Figures 17C-E) so as to provide loops 1016-1019 having members of varying lengths or varying patterns. The free loops 1016 and 1017 of the second sinusoids 1010 may, for example, have a combination of longer and shorter members such as, for example, member 1014a and 1014b respectively. Those skilled in the art will appreciate, therefore, in light of the foregoing, the specific heights, shapes, linearity, non-linearity, curvature, geometric disposition, angular relation of the strut members 1014a-c with respective intervening connective curved segments forming loops 1016-1019 may be modified in any number of ways and still carry out the spirit of the present invention.

[0071] Thus, what is described is a longitudinally flexible stent that utilizes a cell structure to provide excellent coverage of the vessel wall. Similarly, a combination of intersecting vertical and horizontal meander patterns make up this embodiment, wherein the horizontal meander patterns comprise odd 1028o and even 1028e patterns which are preferably mirror images of each other and may intermittently intersect 1025 and 1026 and form cells 1050 which are uniformly distributed along the longitudinal axis of the stent. The general concepts described herein can be utilized to form stents with different configurations than the particular embodiments described herein. For example, the general concepts can be used to form bifurcated stents. The present invention is not limited to what has been particularly shown and described above. Rather, the scope of the present invention is defined by the claims which follow.

[0072] The loops of the higher frequency bands may be of different length and arranged such that some of the loops occupy the space close to one end of the ring and others occupy the other side (figures 17 D and 17E). This arrangement may facilitate a smaller crimped diameter for a given width of struts. It is also possible in this arrangement to shape the loops such that the distance between neighboring struts will be more uniform to decrease the risk of balloon pinching between struts during crimping (figure 17E).